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Technical Report 32-1398

Quality Assurance Monitoring of the Microbiological Aspects of the Sterilization Assembly Development Laboratory

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Preface

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Abstract

The Jet Propulsion Laboratory SADL (Sterilization Assembly Development Laboratory) program was initiated to develop and optimize the techniques, facilities, and procedures necessary for the assembly, test, microbiological monitoring, and sterilization of a capsule system which would satisfy NASA quarantine constraints with minimum effect on capsule reliability.

An important aspect of SADL was the development of the Quality Assurance (QA) functions and procedures associated with the activities required for the microbiological monitoring of the capsule system, including sterility verification of material, the assay technique, certification of the facility, and the monitoring of personnel activity in the facility.

The SADL QA program demonstrated that QA personnel can play an effective role in monitoring microbiological operations by applying the same QA rationale used in their classical role in a hardware program. In particular, the application of QA methods identified the need for improvement in assay methodology and techniques as evidenced by a 0 to 30% variation in contamination of sterile samples over 16 repetitive assemblies. In addition, the QA inspection reports identified the procedural violations occurring during assembly which, when reviewed by the technical personnel, resulted in the identification of the probable cause of 75% of the bio-burden buildup on the capsule.

Quality Assurance Monitoring of the Microbiological Aspects of the Sterilization Assembly Development Laboratory

I. Introduction

The National Aeronautics and Space Administration (NASA) has established a policy of planetary quarantine to prevent the introduction of terrestrial microorganisms to other planets by spacecraft. Compliance with this policy will be accomplished in two steps: assembling such spacecraft capsules in an ultra-clean environment to limit biocontamination levels to a maximum of 10^5 viable organisms, and a prelaunch dry heat sterilization cycle sufficient to reduce the probability of survival of one microorganism to one chance in ten thousand. The JPL Sterilization Assembly Development Laboratory (SADL) was designed and constructed to serve as the pilot plant for the development of the techniques and procedures necessary to assemble such a capsule and to microbiologically assay, sterilize, and certify that it has satisfied the NASA planetary quarantine requirements (Ref. 1).

II. The SADL Program

SADL (Fig. 1) is an integrated spacecraft assembly facility having a gross floor area of 20,000 ft². It contains two Class 100 laminar down-flow clean rooms: one is 20 × 20 × 8 ft high and is used for microbiological experimentation and the development of aseptic subsystem assembly techniques; the other is 30 × 40 × 35 ft high and is used for the development of capsule assembly and microbiological monitoring techniques. Other major features include an ethylene oxide/vacuum chamber, microbiolcgical laboratory, operations support area, terminal sterilization chamber, and other necessary support areas. All collateral equipment for receiving inspection, capsule system testing, spacecraft alignment check, facility certification, and microbiological assay is available.

The hardware used to develop and verify capsule assembly procedures was a Capsule Mechanical Training Model (CMTM) (Fig. 2). It was a 14-ft-diameter mechanical mockup of the major subassemblies which comprise a typical spacecraft capsule and consisted of the following major items: an entry aeroshell, a payload section, eight electronic subsystems, a 4-ft-diameter impact limiter, a parachute canister, a deorbit motor, and a relay-link antenna. After the assembly procedure had been initially developed, the CMTM was assembled and disassembled repeatedly to determine the effect of environment on bio-burden buildup during assembly as well as the adequacy of the assembly procedures. Assemblies for environmental comparison were performed in the high-bay area (approximately a Class 100,000 area), in a Class 100 portable laminar down-flow tent, and in SADL.

The management of the SADL facility and program was under the direction of a project manager, with operating responsibilities vested in a supporting staff which consisted of four technical groups: Facilities Operation,

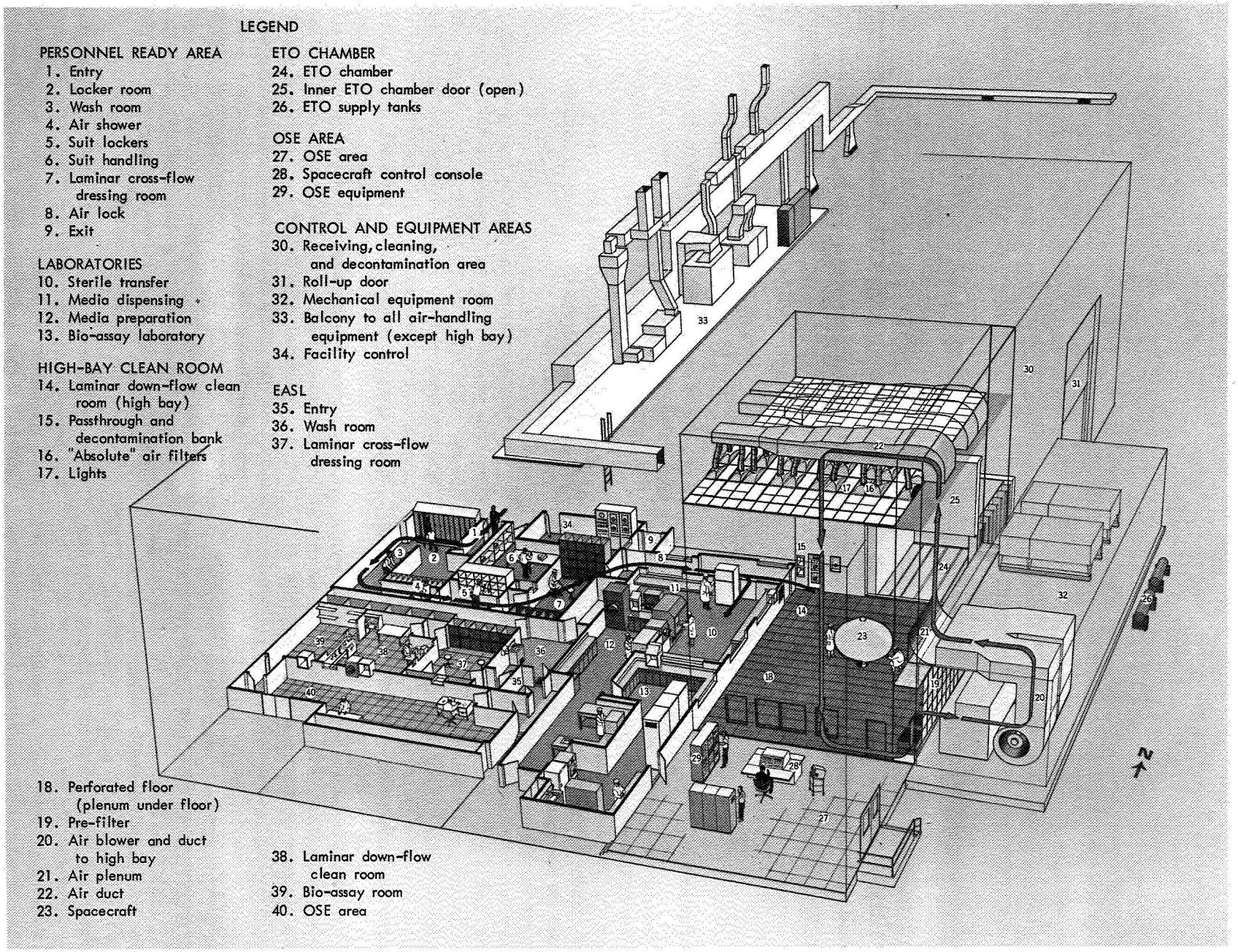

Fig. 1. SADL facility

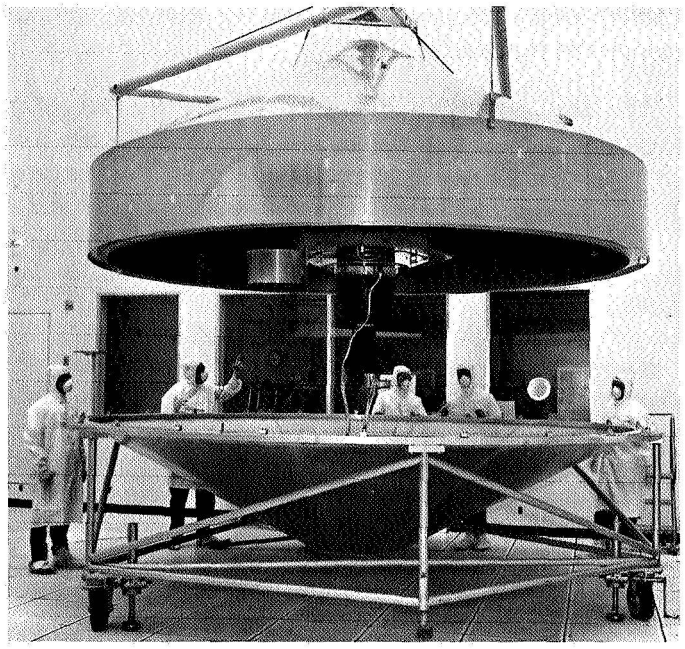

Fig. 2. Assembled CMTM being installed in lower half of sterilization canister

Mechanical Assembly, Microbiology, and Quality Assurance (QA). The responsibility of these organizations was to develop and optimize the techniques and methods for this type of assembly within their respective areas.

The Facilities Operation group operated the SADL facility, monitored the performance of the facility and microbiology laboratory equipment, maintained them to established certification standards, and provided logistic support to the other groups.

The Mechanical Assembly group was responsible for the development of the capsule assembly and system test plans and procedures, and integrated the requirements of the Microbiology and Quality Assurance groups into the CMTM assembly and test plan (*CMTM Assembly in SADL*, JPL SADL Procedure 4-212).

The SADL Microbiology group developed the microbiological plans, which included microbiological certification of the clean rooms, decontamination requirements and standards, capsule microbiological sampling and assay plans, and the operation of the microbiological laboratory (*Microbiological Procedures—Objectives and Requirements*, JPL SADL Procedure 3-200).

The Quality Assurance group formulated and implemented the necessary plans and procedures to assure adherence to the capsule assembly and test requirements as well as the microbiological constraints. The interrelationship of QA with the other disciplines was explicitly established as complete surveillance of all activities and operations affecting the goals of SADL, based on detail QA plans which were approved by the discipline affected.

III. Quality Assurance Program

In supporting the SADL program, the JPL Quality Assurance organization had several motivating factors. JPL is a research and development laboratory; each new spacecraft project undertaken represents, in one area or another, a new technology. While the development of the new technology is basically an engineering responsibility, the Quality Assurance organization must understand that technology in order to accomplish its assigned function.

Participation in the SADL program offered the Quality Assurance group the opportunity to develop the required procedures and techniques as well as to train a key cadre of personnel in spacecraft sterilization procedures and to lay the basis for sound planning for support of an actual flight project (*Quality Assurance Plans—Objectives and Requirements*, JPL SADL Op. Plan 5-100).

The only aspect of the SADL program new to JPL QA was monitoring the microbiological laboratory and associated functions. As is evident from the earlier description, there is no real comparison of problems in assembling the CMTM (a mechanical mockup) vs assembling a Mariner flight-quality spacecraft. However, consistent with the objectives of SADL, a full QA program was initiated which included all the procedures required for a spacecraft hardware project (receiving inspection requirements, spacecraft inspection plan, material review boards, etc.).

The monitoring of the microbiological activities was concentrated in four major areas: certification of material used in microbiological sampling and assay, assay technique, facility microbiological certification, and infractions of personnel procedure. In addition, a contamination review board was established to make disposition of discrepant items in the same manner as a material review board is used to make disposition of discrepant spacecraft hardware.

A. Material Certification

The philosophical approach to the certification of material used in the SADL microbiological laboratory was

not significantly different from that used in the certification of spacecraft hardware. Certification of material employed in the SADL microbiological laboratory was performed to reduce the probability of introducing contamination during sampling and assay, with a resultant generation of invalid data.

The procedures used by Quality Assurance in SADL were simple and straightforward. The Quality Assurance engineer selected a random sample of each item (such as tools, gloves, coupons) to be used during the assembly of the CMTM and delivered it to the SADL microbiological laboratory for assay. The remainder of the lot was then impounded until the samples had been assayed. The samples were normally incubated for 72 hr; however, in case of schedule conflicts, and with the mutual agreement of the Quality Assurance manager and the Microbiology manager in a documented Contamination Review Board action, the material could be used if growth was not observed after 48 hr. At the completion of the incubation period, the Quality Assurance engineer and laboratory microbiologist inspected the samples to verify sterility. If the samples showed no evidence of growth, the Quality Assurance engineer released the material for use. If the samples were contaminated, the material was rejected and not used unless Contamination Review Board authorization was obtained.

B. Assay Technique

A major factor in any R&D program is the validity of the data generated. In the SADL program, the data originated from the microbiological assay of previously sterilized stainless-steel coupons mounted on the CMTM during selected intervals of the assembly process. This assay data formed the basis of the predicted microbiological burden on the CMTM for that assembly. The validity of the data is dependent on the reliability of the assay method and the quality of application of the method during the collection and assay of the samples.

The assay methods used in SADL were in accordance with the requirements of *The NASA Standard Procedures for the Microbiological Examination of Space Hardware* (Ref. 2), and it was the responsibility of Quality Assurance to ensure that the specified methods were used properly. Accordingly, in SADL, Quality Assurance established procedures to ensure that the data generated by the microbiological laboratory was an accurate representation of the samples assayed. This was done by monitoring sample removal from the CMTM to see that specified procedures were used (i.e., sterile forceps, gloves, aseptic removal, etc.), and by inserting control samples in the normal flow (Fig. 3).

The first procedure was very simple: the assembly inspector verified that the material used in the removal process was previously certified and that the coupons were removed in the correct sequence. If the inspector noticed a torn glove or if a coupon was dropped, that information was recorded in the spacecraft master log book.

The utilization of control samples was also a relatively simple function. Prior to the initiation of an assembly sequence, the Quality Assurance engineer and the microbiological engineer identified about 5% of the total CMTM coupons by serial number; these would be substituted for analysis by Quality Assurance coupons. Laboratory personnel then prepared the required number of sterile coupons and inoculated coupons, which were identical in every respect, including containers, to the coupons used on the CMTM.

During the coupon removal process, the Quality Assurance engineer replaced the CMTM coupons with the control coupons and assigned the serial number to the controls prior to releasing the samples to the laboratory for assay. Since the identity of the controls was known

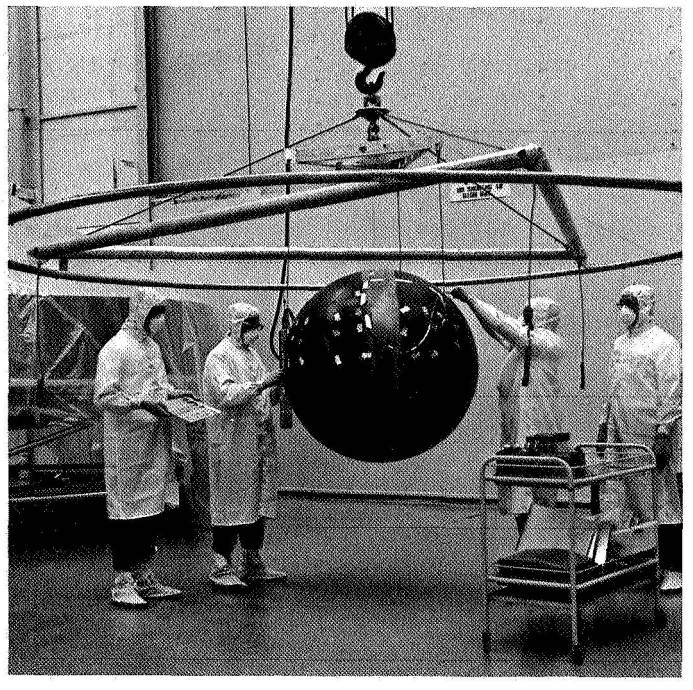

Fig. 3. Quality Assurance monitoring installation of bio-coupons on impact limiter

only to the Quality Assurance engineer and the microbiological engineer, who reported independently of the laboratory organization, security was easily maintained. When the laboratory completed the assay, the data sheets (Fig. 4) were returned to the Quality Assurance engineer for signoff and identification of the control units.

C. Facility Certification

The SADL clean rooms were certified to the requirements of *The NASA Standards for Clean Rooms and Work Stations for the Microbially Controlled Environment* (Ref. 3). It is not the intent of this report to examine details of clean room certification, but rather to discuss briefly the role of Quality Assurance in this activity.

Quality Assurance personnel verified that tests required by the above NASA standards were performed, using previously certified material. In addition, control samples were employed in the manner discussed earlier, except that QA controls also included Rodac and Reyniers plates.

An equally important set of certification standards was established for the collateral equipment used by the microbiological laboratory, including laminar flow benches, incubators, sonicators, ovens, and even such items as a Reyniers air sampler. In addition, all laboratory equipment was put on a mandatory calibration recall cycle under the control of the Quality Assurance organization, and if a given piece of equipment was not recalibrated during the specified period, it was withdrawn from use.

D. Visual Monitoring

Another important function performed by Quality Assurance was the visual monitoring of personnel activity during the assembly sequence to see that all personnel adhered to the SADL dressing procedures, as well as to document abnormal activity during assembly (a torn glove, excessive body contact with hardware or coupons, etc.). Quality Assurance personnel were not required to be trained microbiologists to perform this function. However, microbiologists used the output to check abnormalities in the data. This function will be discussed in more detail in Section IV.

The NASA Quarantine Office is considering establishing a requirement for a permanent visual record of all infractions of clean room discipline. In the program under discussion, an analytical study was conducted to determine the optimum cost-effective method of satisfying such a requirement, concluding that a closed-circuit TV/video tape system would best serve the purpose (Ref. 4). Functional requirements for such a system were also developed for use in SADL; however, it was felt that procurement of the system would be unwarranted at that time.

IV. Meaning and Use of QA Monitoring Data

The sterile QA control coupons indicated in the first few CMTM assemblies that a high level of contamination of the samples was occurring in the microbiological laboratory (Table 1). This information resulted in a number of changes in laboratory techniques and procedures: adding a germicide to the sonicator fluid, making more stringent requirements for dress of personnel, putting Z-lines in laminar-flow benches, and decontaminating gloved hands every tenth sample. The changes greatly reduced the level (quantity), but not necessarily the frequency, of sample contamination. These results indicate that the QA monitoring activity can be used to identify contamination resulting from personnel techniques and procedures as well as from facility and equipment deficiencies. It must be recognized, however, that sample contamination will always be a problem and that QA monitoring itself will not eliminate it.

Table 1. Contaminated sterile coupons

Assembly	Sterile coupons	Coupons contaminated	Contamination, %
High bay 1	17	4	24
High bay 2	20	6	33
High bay 3	40	7	18
Tent 1	19	3	15
Tent 2	40	1	3
Tent 3	40	5	13
Tent 4	48	4	8
Tent 5	48	2	4
Tent 6	38	2	6
SADL 1	44	6	14
SADL 2	79	6	8
SADL 3	64	0	0
SADL 4	64	1	2
SADL 5	64	0	0
SADL 6	64	5	8
SADL 7	64	5	8

Hardware/Environment _____ Number _____ Page _____ Of _____

Operation _____ Date of Assy _____

Assembly Step	Zone	Type of Zone	Assay Site	Assay Site Substituted	Bottle Number	QA Check	QA Control	Method of Assay	Assay Procedure	Aerobes: Vegetative cells (A,B) 24	48	72	Rpt'd	Aerobes: Spores (E,F) 24	48	72	Rpt'd	Anaerobes: Vegetative Cells (C,D) 24	48	72	Rpt'd	Anaerobes: Spores (G,H) 24	48	72	Rpt'd	Fungi 24	48	72	Rpt'd	Total Aerobes	Total Anaerobes	Total Vegetative	Total Spores	Total Fungi	Total Population
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
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									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
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									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												
									A/B					E/F				C/D				G/H												

Sign Off: Microbiology _____

Quality Assurance _____

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Fig. 4. Biological assay data: hardware/environment

The proportion of sterile QA control coupons contaminated vs assembly days for all 83 days of assembly activity is shown in Fig. 5. It should be noted that the assembly days are not in the actual sequence but have been grouped according to test environment. The data indicates that laboratory contamination occurred throughout the test program and, more important, it occurred with a random frequency. Because of this characteristic, a mean level of laboratory contamination can be assumed in the analysis of biological monitoring data, and QA monitoring could ascertain when laboratory contamination has passed the upper confidence limit. At this point, laboratory contamination could significantly affect the biological burden estimate of the item being sampled.

In the SADL program, the number of QA controls was based on the number of CMTM coupons assayed that would represent one QA control per 20 CMTM coupons. Controls on assay procedures and techniques varied from a maximum of 11 to a minimum of two. Some of the random variability observed in Fig. 5 may be due to the changes in control numbers. The data indicate that more meaningful contamination control data would result if a minimum number of QA controls were assayed on a given day, independent of the number of spacecraft samples. Furthermore, if the number of spacecraft samples are large, additional QA coupons would be used, based on a sliding scale of QA controls to spacecraft samples above the minimum level. This would result in lowering the upper confidence limit and increasing the reliability of the measurement.

Inoculated QA control coupons were initially conceived as a tool to measure the effectiveness of the laboratory in accurately determining the contamination level of a sample. However, the contamination levels on the CMTM were lower than the experimental limits of present inoculation and recovery techniques, and use of these coupons was discontinued after several assemblies.

The objective of QA visual monitoring was to document gross violations of assembly and personnel procedures, since such violations could result in abnormal contamination levels. A detailed log of all such violations was maintained by Quality Assurance, and the analysis of that log provided the microbiologist with a "most probable cause" in 75% of the cases of abnormal data (Fig. 6). The documentation of these violations was keyed to major steps during the assembly process rather than to an individual coupon. Unfortunately, the computer program analyzing the data was keyed to the individual coupons, so that when the data is reduced to mean

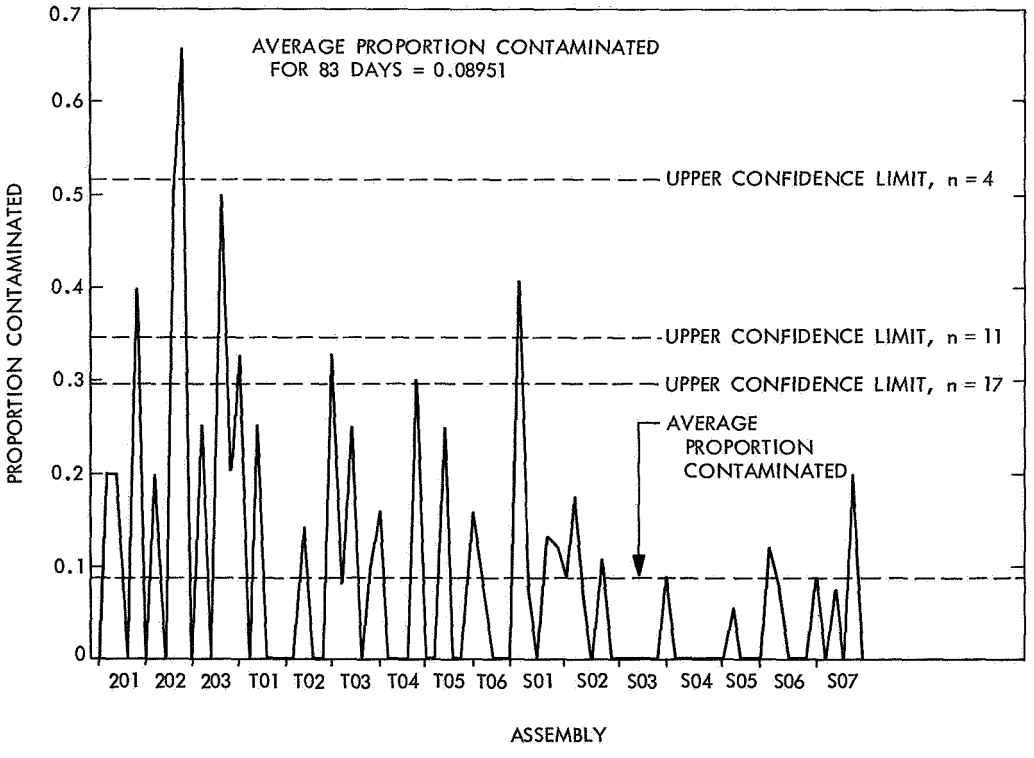

Fig. 5. Proportion of controls contaminated vs assembly days

OPERATION STEP = OP
HIGH BAY ASSEMBLIES = H
SADL CLEAN ROOM ASSEMBLIES = S
LAMINAR FLOW ASSEMBLIES = T

NO SAMPLE = N/S
MEAN = $\bar{X}$
MATRIX = M
AEROBIC VEGETATIVE = AV
AEROBIC SPORES = AS

OP#	MATRIX 1	MATRIX 2	MATRIX 3	T-1 M-1 $\bar{X}$ AV	T-1 M-1 $\bar{X}$ AS	REMARKS	T-2 M-3 $\bar{X}$ AV	T-2 M-3 $\bar{X}$ AS	REMARKS	T-3 M-2 $\bar{X}$ AV	T-3 M-2 $\bar{X}$ AS	REMARKS	T-4 M-3 $\bar{X}$ AV	T-4 M-3 $\bar{X}$ AS	REMARKS	T-5 M-2 $\bar{X}$ AV	T-5 M-2 $\bar{X}$ AS	REMARKS *	T-6 M-3 $\bar{X}$ AV	T-6 M-3 $\bar{X}$ AS	REMARKS	$\bar{X}$ AV	$\bar{X}$ AS	REMARKS
PRE ALCOHOL	0.5	0.5	0.5	0	0		.02	0		.24	.09		.43	.17		.33	0		.61	.04	*			
POST ALCOHOL	0.7	0.7	0.7	0.43	.02		.28	.22		.48	.04		.02	.15		.43	.02		.88	.04	*			
1.0	1.02	1.02	1.02	0.38	.12	BODY CONTACT	0	0		3.75	0	BODY CONTACT	.25	0		.13	0	TENT TURNED BACK	1.62	0				
	1.05	1.05	1.05	7.5	0	BODY CONTACT	0	0		1.0	0		0	0		.50	0	" "	0	0				
	1.07	1.07	1.07	5.0	0	BODY CONTACT	12.5	0	TENT TOUCHED FLOOR	1.20	.20		0	.50		0	0		.25	0				
	1.11	1.10	1.10	0	0		0	0		0	0		0	0		1.0	0		3.0	0				
	1.13	1.12	1.12	0	.03		0	0		0	0		0	0		0	0		1.0	0				
	1.15	1.14	1.15	3.83	.17	BODY CONTACT	19.83	0	CONTAMINATED GLOVES PIC TECH.	0	0		3.0	0		0	0		2.83	.17	BODY CONTACT			
	1.17	1.16	1.17	0	0		0	0		0	0		0	0		0	0		0	0				
	1.19	1.19	1.19	0.2	0		0	0		0	0		0	0		0	0		0	0				
	1.22	1.21	1.22	0.2	0		0	0		0	0		0	0		0	0		0	0				
	1.25	1.23	1.24	0	0		0	0		.66	0		0	0		0	0		0	0				
	1.27	1.25	1.26	1.0	0		0	0		0	0		.33	0		0	0		0	.67				
	1.29	1.27	1.28	0	0		0	0		0	0		0	0		0	0		0	0				
	1.31	1.30	1.30	29	0	BODY CONTACT POSSIBLE STAPHYLOCOCCUS	0	0		0	0		0	0		0	.33		.25	0	EXCESSIVE GARGLE HANDLING			
	1.33	1.32	1.32	0	0		0	0		0	0		0	0		0	0		0	0				
		1.34	1.34	N/S	N/S		0	0		.12	.12		.33	0		0	0		0	0				
	1.36	1.37	1.37	.21	.11	EXPOSED WRIST AREA POSING PROBLEMS	.05	0		.10	.05		3.53	0	BODY CONTACT	.05	0		1.63	0	BODY CONTACT			
2.0	2.02	2.02	2.02	.33	0		19.0	0	BOOTIES ON FLOOR AT ENTRANCE	0	0		.33	0		2.67	0	TENT OPEN DURING COUPON PULLING	0	0				
	2.05	2.05	2.05	1.0	.11		.17	.08	LIMITED TRACES CONTAMINATION FOUND AROUND FROM THESE AREAS	1.08	0		13.3	.17	COVER TOUCHED FLOOR	0	0		3.36	0	IMPROPER GLOVING OF HARDWARE			
	2.07	2.07	2.07	.30	.20		.46	0		1.38	0		15.2	0	" "	.38	0	TENT OPEN DURING COUPON PULLING	.53	0				
3.0	3.02	3.02	3.02	3.35	.12		0	0		1.02	0		.18	.12		.29	0		.29	0				
	3.06	3.06	3.06	49.2	.21	BODY CONTACT ACCEPTABLE	2.19	0	BODY CONTACT	3.27	0		1.27	.14		8.71	0		1.59	0				
		3.08	3.08	N/S	N/S		0	0		0	0		0	.50		0	0		0	0				
	3.09	3.11	3.11	2.33	.06	COVER TOUCHED FLOOR	.31	.02		1.37	.17	COVER ON FLOOR	4.31	.05	EXCESSIVE HANDLING REQUIRED	4.67	0		6.73	0	EXCESSIVE HANDLING OF MAGNUM CLAMP			
4.0	4.04	4.04	4.04	1366	0		0	0		.33	0		0	0		0	0		.33	0				
	4.07	4.07	4.07	.66	0		.10	0		0	0		0	.57		0	0		0	0				
	4.16	4.16	4.16	1.0	0		2.50	0		1.0	0		0	0		2.0	0		0	0				
5.0	5.03	5.03	5.03	0	0		0	0		0	0		0	0		0	0		0	0				
	5.05	5.06	5.06	.40	0		2.0	0	MAGNUM CLAMP CONTAMINATED PIC TECH	.50	.16		.60	0		.10	0		3.0	.30	CONTAMINATED GLOVES QUINN #274 PIC			
	5.09	5.11	5.11	2.20	.20	CONTAMINATED MAGNUM CLAMP	69.0	0		.16	0		0	0		0	0		17.2	0	EXCESSIVE HANDLING			
6.0	6.02	6.01	6.01	.50	0		0	0		0	0		.66	0		0	0		1.0	0				
	6.04	6.03	6.03	2.50	0		1.13	0		0	0		.08	.08		1.67	0		5.0	0				
	6.06	6.06	6.06	.85	0		48.1	0		0	0		0	0		5.25	0		4.67	0				
	6.07	6.07	6.07	6.97	0	BODY CONTACT	28.9	0		.69	.05		4.30	.03	BODY CONTACT	1.65	0		.87	0				
	6.08	6.08	6.08	1.09	.05		43.5	0		9.0	0	TENT OPEN DURING COUPON REMOVAL	17.6	.03		6.91	.07		5.47	.02				
	6.09	6.09	6.09	6.57	.06	TENT OFF FOR 48 HOURS	2.06	.03		N/S	N/S		4.26	.14		1.0	.04	↓	N/S	N/S	ASSEMBLY INCOMPLETE *			
7.0																								
8.0																								
9.0																								

* T.5 DUE TO FIRE IN AIR CONDITIONING SYSTEM, HARDWARE IN HIGH BAY WAS EXPOSED TO SMOKE AND SOOT. DOORS INTO AREA WERE OPEN FOR TWO DAYS AND FIRE DEPARTMENT PERSONNEL WERE IN HIGH BAY AREA IMPROPERLY DRESSED. TENT WAS OPEN DURING MOST OF COUPON REMOVAL.

* T.6 NO SAMPLES TAKEN AT OPERATION #1.0 DUE TO TENT REMOVAL TO STAT ASSEMBLY NOT COMPLETED. SWABS TAKEN AT STEP #0.5 & 0.7 POSSIBLY CONTAMINATED DUE TO FAULTY APETTES USED IN LABORATORY ASSAY, REF. BIO ASSAY DATA 6-6-68

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Fig. 6. CMTM data analysis record

values for each major step (i.e., a collection of coupons), the effect of the violation can be seen, but adjusting the data to remove the effects would require throwing out large blocks of samples. In retrospect, if it had been anticipated that the technique of visual monitoring would be so sensitive, the documentation would have been keyed at the coupon level.

At the present time, a thorough analysis is being made of all the data generated in SADL, and the implications of the results for spacecraft planetary quarantine requirements will be determined. A series of JPL Technical Reports will be issued summarizing the SADL program and data (Refs. 5 and 6).

V. Conclusion

The SADL QA program demonstrated that QA personnel can play an effective role in monitoring microbiological operations by applying the same QA rationale used in their classical role in a hardware program. In particular, the application of QA methods identified the need for improvement in assay methodology and techniques as evidenced by a 0 to 30% variation in contamination of sterile QA samples over 16 repetitive assemblies. In addition, the QA inspection reports identified the procedural violations occurring during assembly which, when reviewed by the technical personnel, resulted in the identification of the probable cause of 75% of the burden buildup on the capsule.

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